K121554

JUN - 8 2012

510(k) Summary
Infusion Innovations, Inc.
Q-Flo™ Closed Male Luer Connector

Submitter Information

Company Name:	Infusion Innovations, Inc.
Company Address:	7514 Girard Avenue La Jolla CA 92037 (858) 456-6116 (858) 777-3375 (fax)
Contact Person:	Babak Nemati, Ph.D. President, CEO Infusion Innovations
Date of Summary:	April 12, 2011

Device Identification

Generic Device Name:	Closed Male Luer Connector
Trade/Proprietary Name:	Q-Flo™ Closed Male Luer Connector
Classification:	Class II
Product Code:	FPA Intravascular Administration Set 21 CFR 880.5440

Predicate Device

The Q-Flo™ Closed Male Luer Connector is of a comparable type and is substantially equivalent to the following predicate devices.

Alaris Safety Male Luer Cardinal Health, Alaris Products K053049 Cleared: January 12, 2006	Spiros Closed Male Luer ICU Medical, Inc. K070532 Cleared: March 20, 2007

Device Description

The Q-Flo™ Closed Male Luer Connector is a sterile, non-pyrogenic, and single-use luer device. It enables clinical personnel to handle fluids, including hazardous materials such as chemotherapy, radioactive isotopes, and blood products when used in conjunction with a compatible female luer connector. This includes the preparation and administration of fluids to the patient and waste handling. This provides

access for the administration of fluids from a container to a patient's vascular system through an administration needle or catheter which is inserted into an artery or vein.

The Q-Flo™ CML connector uses a sequential locking mechanism with a colored visual indicator to provide the user with confirmation of the status of the connection. There are three (3) connection states possible. When the device is not connected to a female luer it is closed and drip-less. When the device is connected to a female luer but the connection is deactivated, the visual indicator is not present and no flow is permitted. Continuing to turn the device and female luer connection together actuates the connection and opens the system to permit flow.

The Q-Flo™ CML connector utilizes the engagement of the luer threads to open the fluid path and, with the silicone sealing member, to provide a leak free state. The action of the thread engagement moves the male luer connector forward and visible to the used thus giving visual confirmation of full connection.

The Q-Flo™ CML connector has been designed with a weight and size to be consistent with IV administration set connections. It weighs less than 2.5 grams and is 12.8 mm in diameter.

There are no questions regarding the new product safety and effectiveness that are raised due to the Q-Flo™ CML connector design.

Intended Use

The Q-Flo™ Closed Male Luer Connector is intended for use by healthcare professionals for connection with standard open female luers when reconstituting, dispensing/transferring, administering, and disposal of potentially hazardous fluids, such as chemotherapy, radioactive isotopes, and blood products, as well as non-hazardous fluids.

Technical Characteristics and Substantial Equivalence

	Q-Flo Closed Male Luer Connector	**Alaris Safety Male Luer**	**Spiros Closed Male Luer**
Functional Use	Needleless connector	Needleless connector	Needleless connector
Engagement States	Disconnected Luer connected/No flow Luer engages female connector and allows flow	Disconnected Luer engages female connector and allows flow	Disconnected Luer engages female connector and allows flow
Residual Volume	0.02 mL	0.03 mL	0.06 mL
Gravity Fluid Flow @ 1 meter height	193 mL/min	97 mL/min	195 mL/min
Syringe Disconnect: Fluid Displacement	Less than 0.05 mL	Not stated	0.01 – 0.03 mL
Multiple Activations	25 activations or 72 hours (whichever occurs first)	50 activations or 72 hours (whichever occurs first)	10 activations
Luer Retention	ISO 594-2(5.4)	ISO 594-2(5.4)	ISO 594-2 (5.4)
Chemical Compatibility	Lipid & alcohol based fluids	Not stated	Lipid & alcohol based fluids
Sterilization Method	Radiation	Radiation	Radiation
Packaging	Peel pouch	Peel pouch or packaged with other IV set components	Peel pouch or packaged with other IV set components

Materials			
Female luer	Polycarbonate	-Polycarbonate	Polycarbonate
Male luer	Polycarbonate	-Polycarbonate	Polycarbonate
External Housing	Copolyester	-Polycarbonate	Polycarbonate
Inner housing or backing	Polycarbonate	-Polypropylene (actuator)	Polycarbonate (poppet)
Sealing surface	Silicone	-Silicone	Silicone

Technological Characteristics

The technological characteristics of the Q-Flo™ Closed Male Luer Connector and the predicate devices were compared. This demonstrated that the Q-Flo™ Closed Male Luer Connector is substantially equivalent to those predicate devices.

Discussion of Nonclinical Tests

Risk analyses were conduct for the Q-Flo™ Closed Male Luer Connector and design verification and validation tests were based on the results of those analyses. All test results meet the acceptance criteria and support that the device is appropriately designed for its intended use. This testing confirmed the physical attributes and device performance meet requirements of the standards listed below.

Characteristic	Standard/Test Method	Device Performance
Biocompatibility	ISO 10993-1	Passed
Dimensional and Performance	ISO 594-2 ISO 8536-4	Passed Passed
Sterility Assurance	ISO 11137-2	Passed

Conclusion

The Q-Flo™ Closed Male Luer Connector device meets the functional claims and intended use as described in the product labeling. The safety and effectiveness are substantially equivalent to the predicate devices Alaris Safety Male Luer and Spiros Closed Male Luer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Infusion Innovations, Incorporated
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

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Re: K121554
Trade/Device Name: Q-Flo Closed Male Luer Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA
Dated: May 24, 2012
Received: May 25, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

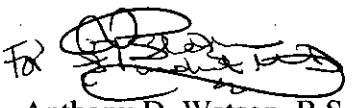
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Q-Flo™ Closed Male Luer Connector

Indications for Use:

The Q-Flo™ Closed Male Luer Connector is intended for use by healthcare professionals for connection with standard open female luers when reconstituting, dispensing/transferring, administering, and disposal of potentially hazardous fluids, such as chemotherapy, radioactive isotopes, and blood products, as well as non-hazardous fluids.

Prescription Use ✓
(Part 21 CFR §801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

6/6/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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